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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,574	07/21/2000	Gregor Cevc	500.1004CON	5661
21874	7590	01/03/2006	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 01/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/621,574	Applicant(s) CEVC, GREGOR	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-33, 35-40, 42-47, 49 and 51-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-33, 35-40, 42-47, 49 and 51-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-30-04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The RCE dated 5-23-05 is acknowledged.

Note: It is unclear from the file as to what claims are pending and what claims are canceled. Applicant should indicate in a clear copy as to what claims are pending and what are canceled. It would appear from the file that claims 34, 41, 48 and 50 are canceled. Claims included in the prosecution are 31-33, 35-40 and 42-47, 49, 51-81.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 31-33, 35-40 and 42-47, 49, 51-81 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what the permeability barrier is as recited in claim 31. This is essential since the dependent claim recites plants. Are plants permeability barriers? Furthermore, according to claim 31, the amount of the lipid in the liquid medium is between 0.1 to 30 %. The dependent claim 38 recites the range between 0.000001 to 10 %. This is inconsistent with claim 31.

Claim 46 is confusing. Line 1 of A recites "forming transfersomes by combining a lipid and a surface active agent that can solubilize said lipid in a suitable medium". If the transfersomes are already formed what is the point in determining the ratio of the lipid to surface-active agent afterwards? This claim is a method of manufacturing claim.

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Therefore, method steps of how the transfersomes are formed should be clearly recited in the claims.

It is unclear how sulfatide is a lipid as recited in claim 58.

There are two claims with the number '58'. The examiner presumes the first one was a typographical error and should have read as 57.

Reciting generic class of compounds with specific compounds in claim 60 is improper. For example, the claim recites, deoxycholate and also sodium deoxycholate and several other deoxycholates.

It is unclear from claim 67 whether the phosphate salts and sulfate salts are for all the Markush members.

'said agent' in claim 72 lacks an antecedent basis in claim 31.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 31-33, 35-40, 42, 46-47, 49, 52-60, 63-69, 70-71, 73-76, 78-80 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0220 797 of record.

EP discloses bilayer compositions containing a drug, claimed amphiphilic lipids and surfactants in ratios falling within the broad claimed ratios. The preparations are either multilamellar or unilamellar (SUVs and

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LUVs)) (page 2, lines 10-50, examples, examples 5, 11, 15 in particular). The method of preparation involves mixing of the components. Since EP recites specific ratios of components, the determining the ratios of the lipid to surface active agent is implicit in EP. Since the method of preparation is the same, the burden is shifted to applicant to show that the bilayer structures in EP are different from instant bilayer structures which applicant calls 'transfersomes'.

Instant claim 38 recites the concentrations of lipid 'for application on plants'. This is an intended use limitation and therefore, the prior art still reads on said claim 38.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 42, 43, 51, 61-62, 72 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0220 797 in view of Lau (5,104,661).

The teachings of EP have been discussed above. What is lacking in EP is the teaching that insulin or growth modulating agent or a pesticide is the active agent. Encapsulation of active agents such as these would have been obvious to one of ordinary skill in the art with a reasonable expectation of success, since the reference of Lau shows the routine use of bilayered structures for the

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encapsulation of insulin, pesticides and growth regulating agents (note abstract, col. 3, lines 53-55 and col. 5, lines 17-32).

7. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0220 797 in view of Quinn (4,666,747).

The teachings of EP have been discussed above. What is lacking in EP is the teaching that an attractant or a pheromone or pesticides is the active agent.

Encapsulation of active agents such as attractants and pheromones would have been obvious to one of ordinary skill in the art with a reasonable expectation of success, since the reference of Quinn shows the routine use of bilayered structures for the encapsulation of these agents (abstract, col. 5, lines 45-67 and claim 9).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 31-33, 35-40 and 42, 46-47, 49, 51-81 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

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unpatentable over claims 199-224 of copending Application No. 09/555,986. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications are drawn to the same compositions and method of preparation and the ratios of the lipid to the surfactant recited in instant claims fall within the generic terms in instant claims. Instant claims thus, are anticipated by the claims in the copending application in terms of ratios. Instant claims are generic with respect to the active agent whereas the claims in the copending application recite insulin as one of the active agents. It would have been obvious to one of ordinary skill in the art to encapsulate any active agent with a reasonable expectation of success since bilayer structures are known as drug carriers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 46-47, 49, 51-69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-33 and 49-92 of copending Application No. 09/284,683. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications are drawn to the same compositions and method of preparation

11. Claims 31-33, 35-40, 42-45 and 70-76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,165,500. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims and the claims in said copending application are drawn to the method of producing preparations for

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transporting an active agent. Instant claims recite that the agent is transported through permeation barriers and instant claims recite skin and mucous membranes. Claims in both applications recite the same four component combination and the method involves mixing the components and instant claims in addition recite specific ratios of the lipid and surfactant. Instant claims are anticipated by the claims of said copending application which are generic with respect to the ratios.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Group 1500